

REMARKS

Claims 2-21 of the rejection under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Claims 6-21 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Dawson et al. (WO 99/37303) (hereinafter Dawson et al.) in view of Howard et al. (WO 01/27068) (hereinafter Howard et al.). Claims 2-21 are pending in the present application. Claims 1, 22-30 have been withdrawn from further consideration by the Examiner under 37 C.F.R. §1.142(b) as allegedly drawn to a non-elected invention. Applicant reserve the right to file one or more divisional applications directed to the subject matter of claims 1 and 22-30.

This response addresses each of the Examiner's rejections. Favorable consideration of pending claims is therefore respectfully requested.

Claims 2-12 has been rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. The Examiner specifically alleges that the combination of SRI with another pharmaceutical agent such as a GABA-A agonist is not well established.

In response, Applicant respectfully submits that the *in vitro* data presented in the application provides that all the title compounds of Formula I and II had IC₅₀ values of about less than or equal to 250nM for SRI, about less than or equal to 1000nM for dopamine reuptake inhibition and about less than or equal to 1000nM for epinephrine reuptake inhibition.

Applicant respectfully submits that the combination of a GABA-A 2/3 agonist and a SRI antidepressant agent would manifest the desired effective treatment of anxiety or depression with routine experimentation owing to the demonstrated IC₅₀ values of the compounds described in the specification. Applicant further respectfully submits that the *in vitro* evidence presented is more than sufficient to satisfy the requirements of 35 U.S.C. §112, first

paragraph. Applicant is unaware of any requirement to show “a likelihood of *in vivo* activity” for the uses being claimed.

Accordingly, the rejection of claims 2-21 under 35 U.S.C. §112, first paragraph is overcome and withdrawal thereof is respectfully requested.

Claims 6-21 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Dawson et al. in view of Howard et al. Dawson et al. discloses a pharmaceutical composition comprising GABA-A 2/3 agonist and a selective serotonin reuptake inhibitor. The Examiner admits that Dawson et al. do not disclose any specific chemical structure of serotonin reuptake inhibitors. The Examiner alleges that Howard et al. teach compounds having the same formula as Formula II of the instant application.

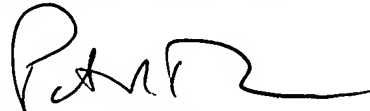
In response, Applicant respectfully submits that the combination of Dawson et al. and Howard et al. do not suggest or motivate the skilled artisan to achieve the pharmaceutical composition comprising a composition comprising gaboxadol (4,5,6,7-tetrahydroisoxazolo[5,4-c]pyridin-3-ol); ganaxolone (3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one); fengabine (2-[(butylimino)-(2-chlorophenyl)methyl]-4-chlorophenol); 2-(4-methoxyphenyl)-2,5,6,7,8,9-hexahydro-pyrazolo[4,3-c]cinnolin-3-one; 7-cyclobutyl-6-(2-methyl-2H-1,2,4-triazol-3-ylmethoxyl)-3-phenyl-1,2,4-triazolo[4,3-b]pyridazine; (3-fluoro-4-methylphenyl)-N-({1-[(2-methylphenyl)methyl]-benzimidazol-2-yl}methyl)-N-pentylcarboxamide; and 3-(aminomethyl)-5-methylhexanoic acid.

Moreover, Applicant submits that the Examiner’s rejection presents a classic case of hindsight reconstruction of the invention, which is expressly prohibited under the law.

Accordingly, the rejection of claims 6-21 under 35 U.S.C. §103(a) is overcome and withdrawal thereof is respectfully requested.

Thus, the present application is in condition for allowance which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

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